

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Polyakov, Igor <i>et al.</i>	Examiner: Minnifield, Nita M.
Serial No.:	10/828,790	Group Art Unit: 1645
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For:	DERMATOMYCOSIS VACCINE	

Commissioner for Patents  
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**DECLARATION OF DR. IGOR POLYAKOV UNDER 37 C.F.R. § 1.132**

Sir:

I, Igor Polyakov, solemnly state and declare as follows:

1. My technical background is as follows:

I am a trained veterinary surgeon having received a diploma in Russia from the Moscow Veterinary Academy, in 1976.

I did a post-graduate study at the Laboratory of mycology and antibiotics of Kovalenko All Union Institute of Experimental Veterinary Medicine from 1978 to 1981 and received a PhD in the year 1981. I joined the Laboratory of mycology and antibiotics of Kovalenko All Union Institute of Experimental Veterinary Medicine in 1981 as researcher and in 1989 to 1992 made Doctor of Science graduate work in the same Laboratory. Since 1993 I have worked as a scientific consultant for the company Boehringer Ingelheim Vetmedica GmbH in the area of mycosis vaccine development. Since 1999 I have been working for the BINOMED GmbH, Germany, where I am engaged in the development of human and veterinary vaccine products.

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2. I am a co-inventor of the above-identified patent application, and I am familiar with the subject matter of the above-identified patent application.
3. I am familiar with the USPTO Office Action dated October 5, 2004 in the above-identified application.
4. Under my responsibility and control, I supervised the production and evaluation of various dermatomycosis vaccines.
5. The vaccines of the present invention were prepared essentially according to the method disclosed in the above-identified application. Several examples of various combination vaccines comprising the fungal strains of the present invention are described in paragraphs (¶) 7 to 12 herein. Examples of single strain vaccines are described in paragraph (¶) 13 herein. Efficacy of all the vaccines described herein was evaluated, and the results are shown in Table 1, attached hereto. All of the challenge experiments described herein were performed in the absence of adjuvants.
6. There are minor, insubstantial differences between the method for preparing the vaccines disclosed in the above-identified application and the methods described herein. Such minor differences include: cultivating temperature (varied between 25°C and 28°C), time of cultivation (varied between 25 and 28 days), and the composition of the aqueous solution containing fermented hydrolyzed muscle protein (varied between 0.3 to 1%), glucose (varied between 5 to 10%) and yeast extract (varied between 0.1 to 1%). It is in the knowledge and reflects the practice of a person skilled in the art that these parameters are alterable within the small ranges mentioned above, without resulting in significant change to the properties of the vaccines.
7. Production and efficacy of a dermatomycosis vaccine comprising three fungal strains:
  - 7.1 In order to produce a vaccine comprising three fungal strains, as claimed and found allowable in parent US patent application Serial No. 10/085,703, cultures of the strains *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277) and *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No.

DSM 7279) were taken. To produce one liter of vaccine, the cultures were grown in malt-extract-agar at 26°C for 25 days. Each culture was grown in 8 matress flasks. The fungal mass was then lifted off, homogenized, placed in 400 ml of solution and added to each mixer. The solution used was an aqueous solution containing 0.3% fermented hydrolyzed muscle protein, 2% glucose and 0.1% yeast extract. The concentration of microconidia was brought to 60 million per ml of homogenate. After 2, days 333 ml of each culture in suspension was taken and mixed in a single container.

To inactivate the homogenate mixture, Thiomersal was added directly to the cell suspension in the ratio 1:20000. Thiomersal (50 mg) was added for every liter of homogenate. The cell mixture was allowed to stand at room temperature for 2 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 7.2 In order to evaluate efficacy, the vaccine produced according to ¶7.1 was used in challenge experiments. Rabbits were immunized with 1.0 ml of the vaccine. In the same day, the animals were challenged with a combination of virulent strains *Trichophyton sarkisovii* and *Trichophyton verrucosum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 2 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks) or with virulent *Trichophyton mentagrophytes* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 million spores over about 2 x 2 cm in the shaved area. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved flank). On the 14<sup>th</sup>, 20<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>, 28<sup>th</sup> and 35<sup>th</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

0 = no symptoms

1 = hyperaemia of the skin in the area of fungal infection

- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection
- 5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 1, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge with *Trichophyton sarkisovii* and *Trichophyton verrucosum* and in day 25-28 after challenge with *Trichophyton mentagrophytes*.

8. Production and efficacy of a dermatomycosis vaccine comprising four fungal strains:

- 8.1 In order to produce one liter of a vaccine comprising four fungal strains, cultures were taken of the strains: *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) and *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276) and grown in malt-extract-agar at 27°C for 28 days. Each culture was grown in 7 matress flasks. The fungal mass was then lifted off, homogenized, placed in 250 ml of solution and added to each mixer. The solution used was an aqueous solution containing 0.5% fermented hydrolyzed muscle protein, 3% glucose and 0.2% yeast extract. The concentration of microconidia was brought to 80 million per ml of homogenate. After 2 days, 250 ml of each culture in suspension was taken and mixed in a single container.

To inactivate the homogenate mixture, Thiomerol was added directly to the cell suspension in the ratio 1:20000. Thiomerol (50 mg) was added for every liter of homogenate. The cell mixture was allowed to stand at room temperature for 4 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 8.2 In order to evaluate efficacy, the vaccine produced according to 8.1 was used in challenge experiments. Rabbits were immunized with 1.0 ml of the vaccine. In the

same day, the animals were challenged with a combination of virulent strains *Trichophyton sarkisovii* and *Trichophyton verrucosum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 2 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.5 ml of absolute ethanol had been applied to the shaved both flanks) or with virulent *Trichophyton mentagrophytes* and *Trichophyton equinum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks). On the 14<sup>th</sup>, 20<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>-28<sup>th</sup> and 33<sup>rd</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

- 0 = no symptoms
- 1 = hyperaemia of the skin in the area of fungal infection
- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection
- 5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 2, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge.

9. Production and efficacy of a dermatomycosis vaccine comprising four fungal strains:

- 9.1 In order to produce one liter of a vaccine comprising four fungal strains, cultures were taken of the strains: *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) and *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275) and grown in malt-extract-agar at 26°C for 25 days. Each culture was grown in 9 mattress flasks. The fungal mass was then lifted off, homogenized, placed in 250 ml of solution and added to each mixer.

The solution used was an aqueous solution containing 0.1% fermented hydrolyzed muscle protein, 5% glucose and 0.2% yeast extract. The concentration of microconidina was brought to 70 million per ml of homogenate. After 2 days, 250 ml of each culture in suspension was taken and mixed in a single container.

To inactivate the homogenate mixture, Thiomersal was added directly to the cell suspension in the ratio 1:20000. Thiomersal (50 mg) was added for every liter of homogenate. The cell mixture was allowed to stand at room temperature for 2 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 9.2 In order to evaluate efficacy, the vaccine produced according to 9.1 was used in challenge experiments. Rabbits were immunized with 1.0 ml of the vaccine. In the same day, the animals were challenged with a combination of virulent strains *Trichophyton sarkisovii* and *Trichophyton verrucosum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 2 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks) or with virulent *Trichophyton mentagrophytes* and *Microsporum canis* var. *distortum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks). On the 14<sup>th</sup>, 20<sup>th</sup>-21<sup>st</sup>, 25<sup>th</sup>-28<sup>th</sup> and 35<sup>th</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

- 0 = no symptoms
- 1 = hyperaemia of the skin in the area of fungal infection
- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection

5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 3, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge.

10. Production and efficacy of a dermatomycosis vaccine comprising four fungal strains:

- 10.1 In order to produce one liter of a vaccine comprising four fungal strains, cultures were taken of the strains: *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) and *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281) and grown in malt-extract-agar at 28° C for 21 days. Each culture was grown in 9 matrices flasks. The fungal mass was then lifted off, homogenized, placed in 250 ml of solution and added to each mixer. The solution used was an aqueous solution containing 0.3% fermented hydrolyzed muscle protein, 5% glucose and 0.4% yeast extract. The concentration of microconidia was brought to 60 million per ml of homogenate. After 2 days, 250 ml of each culture in suspension was taken and mixed in a single container.

To inactivate the homogenate mixture, Thiomersal was added directly to the cell suspension in the ratio 1:20000. Thiomersal (50 mg) was added for every liter of homogenate. The cell mixture was allowed to stand at room temperature for 3 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 10.2 In order to evaluate efficacy, the vaccine produced according to ¶10.1 was used in challenge experiments. Rabbits were immunized with 1.0 ml of the vaccine. In the same day, the animals were challenged with a combination of virulent strains *Trichophyton sarkisovii* and *Trichophyton verrucosum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 2 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left

and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks) or with virulent *Trichophyton mentagrophytes* and *Microsporum canis* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks). On the 14<sup>th</sup>, 20<sup>th</sup>-21<sup>st</sup>, 25<sup>th</sup>-28<sup>th</sup> and 35<sup>th</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

- 0 = no symptoms
- 1 = hyperaemia of the skin in the area of fungal infection
- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection
- 5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 4, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge.

11. Production and efficacy of a dermatomycosis vaccine comprising four fungal strains:

- 11.1 In order to produce one liter of a vaccine comprising four fungal strains, cultures were taken of the strains: *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-727/1311/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) and *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280) and grown in malt-extract-agar at 26°C for 28 days. Each culture was grown in 8 matreass flasks. The fungal mass was then lifted off, homogenized, placed in 250 ml of solution and added to each mixer. The solution used was an aqueous solution containing 0.3% fermented hydrolyzed muscle protein, 5% glucose and 0.1% yeast extract. The concentration of microconidia was brought to 80 million per ml of homogenate. After 2 days, 250 ml of each culture in suspension was taken and mixed in a single container.



To inactivate the homogenate mixture, Thiomersal was added directly to the cell suspension in the ratio 1:20000. Thiomersal (50 mg) was added for every liter of homogenate. The cell mixture was allowed to stand at room temperature for 2 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 11.2 In order to evaluate efficacy, the vaccine produced according to ¶11.1 was used in challenge experiments. Rabbits were immunized with 1.0 ml of the vaccine. In the same day, the animals were challenged with a combination of virulent strains *Trichophyton sarkisovii* and *Trichophyton verrucosum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 2 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks) or with virulent *Trichophyton mentagrophytes* and *Microsporum canis* var. *obesum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks). On the 14<sup>th</sup>, 20<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>-28<sup>th</sup> and 35<sup>th</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

- 0 = no symptoms
- 1 = hyperaemia of the skin in the area of fungal infection
- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection
- 5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 5, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge.

12. Production and efficacy of a dermatomycosis vaccine comprising five fungal strains:

- 12.1 In order to produce one liter of a vaccine comprising five fungal strains, cultures were taken of the strains: *Trichophyton sarkisovii* Strain No. VKPGF-541/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276) and *Micrasporum gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) and grown in malt-extract-agar at 28°C for 25 days. Each culture was grown in 8 mattress flasks. The fungal mass was then lifted off, homogenized, placed in 250 ml of solution and added to each mixer. The solution used was an aqueous solution containing 0.4% fermented hydrolyzed muscle protein, 5% glucose and 0.2% yeast extract. The concentration of microconidia was brought to 90 million per ml of homogenate. After 2 days, 200 ml of each culture in suspension was taken and mixed in a single container.

To inactivate the homogenate mixture, Thiomersal was added directly to the cell suspension in the ratio 1:20000. Thiomersal (50 mg) was added for every liter of homogenate. The cell mixture was allowed to stand at room temperature for 2 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 12.2 In order to evaluate efficacy, the vaccine produced according to §12.1 was used in challenge experiments. Rabbits were immunized with 1.0 ml of the vaccine. In the same day, the animals were challenged with a combination of virulent strains *Trichophyton sarkisovii* and *Trichophyton verrucosum* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 2 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application,

0.3 ml of absolute ethanol had been applied to the shaved both flanks) or with virulent *Trichophyton mentagrophytes* and *Microsporum gypsum canis* (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 million spores over about 2 x 2 cm in the shaved area. Each rabbit in two places (left and right side of body) was challenged. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved both flanks). On the 14<sup>th</sup>, 20<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>-28<sup>th</sup> and 35<sup>th</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

- 0 = no symptoms
- 1 = hyperaemia of the skin in the area of fungal infection
- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection
- 5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 6, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge.

13. Production and efficacy of a dermatomycosis vaccine comprising a single fungal strain:

- 13.1 In order to produce one liter of a vaccine comprising a single fungal strain, cultures were taken of the strains: *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7273) and *Microsporum gypsum* Strain No. VKPGF-729/59 (accession No. DSM 7274) and grown separately in malt-extract-agar at 28°C for 25 days. Each culture was grown in 12 mattress flasks. The fungal mass was then lifted off, homogenized, placed in 1000 ml of solution and

added to each mixer. The solution used was an aqueous solution containing 0.3% fermented hydrolyzed muscle protein, 5% glucose and 0.1% yeast extract. The concentration of microconidia was brought to 80 million per ml of homogenate. After 4 days, 1000 ml of each culture in suspension was inactivated.

To inactivate the homogenate mixture, Thiomersal was added directly to the cell suspension in the ratio 1:20000. Thiomersal (50 mg) was added for every liter of homogenate. The cells were allowed to stand at room temperature for 2 days.

The resulting vaccine was bottled, checked for sterility, safety and immunogenic properties in accordance with accepted methods, and kept refrigerated at 4°C.

- 13.2 In order to evaluate efficacy, rabbits were immunized with one of the single vaccines produced according to ¶13.1. Rabbits were immunized with 1.0 ml of the vaccine. In the same day, the animals were challenged with the corresponding virulent strain of the vaccine (rabbits were infected on skin by distributing with 0.5 ml of the spore suspension containing approximately 1 to 2 million spores over about 2 x 2 cm in the shaved area. Before fungus cell suspension application, 0.3 ml of absolute ethanol had been applied to the shaved flank). On the 14<sup>th</sup>, 20<sup>th</sup>-21<sup>st</sup>, 25<sup>th</sup>-28<sup>th</sup> and 35<sup>th</sup>-36<sup>th</sup> day of the study, the animals were observed and clinical symptoms were evaluated on the basis of the following scoring system:

- 0 = no symptoms
- 1 = hyperaemia of the skin in the area of fungal infection
- 2 = single spots of scaling
- 3 = scaling of the skin in the area of fungal infection
- 4 = thin small crusts in the area of fungal infection
- 5 = scab-like crusts in the area of fungal infection

The efficacy results obtained are shown in Table 1, Example 7, attached hereto. The results demonstrate that all vaccinated animals were free from clinical symptoms of dermatomycosis in day 21-28 after challenge.

From the above experiments and results, I conclude that the vaccines according to the invention of the above-identified patent application are described in such a way as to enable one skilled in the art to make and/or use the invention. Furthermore, I conclude that such activity results would have been both surprising and unexpected to one of ordinary skill in the art of the subject matter of the invention.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

23.03.2005

Signature:



Igor Polyakov

Table 1

Vaccines	Number of animals in challenge test	The culture for challenge (virulent strain)	Efficacy of vaccination
<b>Example 1</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278), <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277) and <i>Trichophyton mentagrophytes</i> Strain No. VKPGF-930/1032 (accession No. DSM 7279)	5	<i>Trichophyton sarkisovii</i> , <i>T. verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton mentagrophytes</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 25-28 after challenge
<b>Example 2</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278), <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277), <i>Trichophyton mentagrophytes</i> Strain No. VKPGF-930/1032 (accession No. DSM 7279) and <i>Trichophyton equinum</i> Strain No. VKPGF-929/381 (accession No. DSM 7276)	5	<i>Trichophyton sarkisovii</i> , <i>T. verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton mentagrophytes</i> , <i>Trichophyton equinum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
<b>Example 3</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278), <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277), <i>Trichophyton mentagrophytes</i> Strain No. VKPGF-930/1032 (accession No. DSM 7279) and <i>Microsporum canis</i> var. <i>distortum</i> Strain No. VKPGF-728/120 (accession No. DSM 7275)	5	<i>Trichophyton sarkisovii</i> , <i>T. verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton mentagrophytes</i> , <i>Microsporum canis</i> var. <i>distortum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
<b>Example 4</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278), <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277), <i>Trichophyton mentagrophytes</i> Strain No. VKPGF-930/1032 (accession No. DSM 7279) and <i>Microsporum canis</i> Strain No. VKPGF-928/193 (accession No. DSM 7281)	5	<i>Trichophyton sarkisovii</i> , <i>T. verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton mentagrophytes</i> , <i>Microsporum canis</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge

<b>Example 5</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278), <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277), <i>Trichophyton mentagrophytes</i> Strain No. VKPGF-930/1032 (accession No. DSM 7279) and <i>Microsporum canis</i> var. <i>obesum</i> Strain No. VKPGF-727/1311 (accession No. DSM 7280)	5	<i>Trichophyton sarkisovii</i> , <i>T. verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton mentagrophytes</i> , <i>Microsporum canis</i> var. <i>obesum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
<b>Example 6</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278), <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277), <i>Trichophyton mentagrophytes</i> Strain No. VKPGF-930/1032 (accession No. DSM 7279) <i>Trichophyton equinum</i> Strain No. VKPGF-929/381 (accession No. DSM 7276) and <i>Microsporum gypsum</i> Strain No. VKPGF-729/59 (accession No. DSM 7274)	5	<i>Trichophyton sarkisovii</i> , <i>T. verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton mentagrophytes</i> , <i>T. equinum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Microsporum gypsum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
	5	<i>Trichophyton sarkisovii</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
<b>Example 7</b> <i>Trichophyton sarkisovii</i> Strain No. VKPGF-551/68 (accession No. DSM 7278),	5	<i>Trichophyton verrucosum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
<b>Example 7</b> <i>Trichophyton verrucosum</i> Strain No. VKPGF-931/410 (accession No. DSM 7277),	5	<i>Trichophyton mentagrophytes</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
<b>Example 7</b> <i>Trichophyton equinum</i> Strain No. VKPGF-929/381 (accession No. DSM 7276)	5	<i>Microsporum canis</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge

Example 7 <i>Microsporum canis</i> var. <i>obesum</i> Strain No. VKPGF-727/1311 (accession No. DSM 7280)	5	<i>Microsporum</i> <i>canis</i> var. <i>obesum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
Example 7 <i>Microsporum canis</i> var. <i>distortum</i> Strain No. VKPGF-728/120 (accession No. DSM 7275)	5	<i>Microsporum</i> <i>canis</i> var. <i>distortum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge
Example 7 <i>Microsporum gypsum</i> Strain No. VKPGF-729/59 (accession No. DSM 7274)	5	<i>Microsporum</i> <i>gypsum</i>	All vaccinated animals were free from clinical symptoms of dermatophytosis in day 21-28 after challenge



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